UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOEL BATZOFIN, M.D., Plaintiff, v. CYNOSURE, LLC, Defendant.	Case No.: **COMPLAINT**

Plaintiff JOEL BATZOFIN, M.D. ("Batzofin" or "Plaintiff"), by his attorneys, as and for his Complaint, as against the Defendant, CYNOSURE, LLC., ("Cynosure" or "Defendant"), respectfully alleges upon information and belief as follows:

PARTIES

1. Plaintiff Batzofin is a citizen of the State of California, residing in Laguna Niguel, California. Plaintiff Batzofin is the sole owner of Batzofin Fertility Services P.C. which conducted business in New York City as New York Fertility Services ("Batzofin Fertility") until April 30, 2019,

2. Defendant Cynosure is a Delaware corporation with its headquarters in Westford, Massachusetts, and was formerly known as Cynosure, Inc. Cynosure, LLC is registered to conduct business in New York.

JURISDICTION AND VENUE

3. This Court has diversity jurisdiction over this case under 28 U.S.C. section 1332 because Plaintiff is a citizen of a State other than the citizenship of Defendant. The amount in controversy is alleged to be over the minimum requirement of $75,000. Venue is proper here as well because a substantial part of the events or omissions giving rise to the claim occurred in this

District.

FACTUAL BACKGROUND

4. This action concerns Plaintiff's purchase, and Batzofin Fertility's financing of that purchase, of a medical device sold by Defendant that it denoted as the MonaLisa Touch. Plaintiff Batzofin first learned of the MonaLisa Touch through direct marketing efforts by Cynosure that included emails sent by Cynosure directly to him during August to October 2016. Some of these emails included invitations to Cynosure seminars about the MonaLisa Touch that included the additional enticement of a steak dinner or lunch. Plaintiff Batzofin attended one such Cynosure sponsored steak dinner seminar in Manhattan in or about October 2016. This dinner seminar included a presentation by Dr. Mickey Karam, a paid consultant for Cynosure who made a presentation extolling the benefits of using the MonaLisa Touch to treat patients suffering from symptoms of Vulvovaginal atrophy ("VVA"), which include vaginal and vulvar dryness, dyspareunia, burning, itching, and irritative symptoms of the lower urinary tract (frequency, urgency, dysuria), including for those who had completed treatment for breast cancer, in whom hormone therapy was contraindicated. Shortly thereafter, Plaintiff Batzofin attended another Cynosure sponsored seminar on Long Island at which the same representations were made by the Cynosure sponsored speaker that Dr. Karam made at the earlier seminar about the benefits of using the MonaLisa Touch to treat patients suffering from symptoms of VVA. At these seminars, numerous Cynosure employees, including Cynosure sales representative Scott Rosenblatt, aggressively pursued Plaintiff Batzofin to convince him to purchase a MonaLisa Touch.

5. Shortly following these seminars and in October 2016, Scott Rosenblatt, together with other Cynosure representatives, met with Plaintiff Batzofin at Batzofin Fertility's office in

Manhattan to continue Cynosure's efforts to induce Plaintiff Batzofin to agree to purchase a MonaLisa Touch. During this meeting, Scott Rosenblatt echoed the representations that were made at the Cynsoure sponsored seminars and represented that the MonaLisa Touch was a safe and effective treatment for patients suffering from symptoms of VVA. Scott Rosenblatt also represented that the MonaLisa Touch was approved by the United States Food and Drug Administration ("FDA") for the treatment of the symptoms of VVA. This representation was integral to Plaintiff Batzofin's decision to purchase the MonaLisa Touch as Plaintiff Batzofin would not have purchased this medical device unless it was FDA approved for the treatments for which Cynosure marketed it and for which he intended to use it. A day or two later, Scott Rosenblatt returned to Plaintiff Batzofin's office and brought with him a representative of Ascentium Capital LLC ("Ascentium Capital") to offer its ability to finance an acquisition of a MonaLisa Touch.

6. On October 31, 2016, Plaintiff Batzofin, executed an agreement for the purchase of a MonaLisa Touch CO2 Laser Workstation ("MonaLisa Touch"), and related products, for a total cost of $155,750.00. Concurrently, Batzofin Fertility entered into an agreement with Ascentium Capital to finance the purchase through Ascentium Capital. Plaintiff Batzofin signed the financing agreement on behalf of Batzofin Fertility and personally guaranteed it. Pursuant to the finance agreement, a total of $196,770 would be owed with the last payment due in May 2022. Plaintiff acted in concert with Batzofin Fertility in connection with the purchase and financing of the acquisition of the MonaLisa Touch at issue. Batzofin Fertility has assigned any and all claims it may have against Defendant to Plaintiff Batzofin.

7. Plaintiff took delivery of the MonaLisa Touch on November 18, 2016 at Batzofin Fertility Service's offices in New York City.

8. Defendant's Sales Representative made the representations described in paragraph 5 above, to Plaintiff in order to induce him to purchase and finance the purchase of the MonaLisa Touch.

9. Defendant also provided marketing materials to Plaintiff for use in marketing the MonaLisa Touch to Plaintiff Batzofin's patients. These marketing materials highlighted the use of the MonaLisa Touch to treat the symptoms of VVA. As a direct result of the representations made and marketing materials provided by Defendant regarding the MonaLisa Touch, Plaintiff Batzofin included similar representations on Batzofin Fertility's website and in its office, touting the treatments offered by the MonaLisa Touch – to treat the symptoms of VVA.

10. The purchase agreement included a one-year service agreement. On or about, September 27, 2017, Plaintiff Batzofin agreed to a one-year extension in this service agreement and paid Cynosure the sum of $5,000.

11. On July 30, 2018, the FDA issued a warning to "patients considering any . . . procedure or procedures intended to treat vaginal conditions and symptoms related to menopause" . . .and to "health care providers who perform vaginal procedures using energy-based devices" to "alert patients and health care providers that the use of energy-based lasers to perform . . . non-surgical vaginal procedures to treat symptoms related to menopause . . . may be associated with serious adverse events [and that] [t]he safety and effectiveness of energy-based devices for treatment of these conditions has not been established." (emphasis added). (the "July 30. 2018 FDA Warning").

12. The FDA went on to state that "[t] o date, we have not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause . . ." (emphasis added) but was "aware that certain device manufacturers

may be marketing their energy-based medical devices for vaginal 'rejuvenation'" (which it defined to include the typical vaginal symptoms of menopause).

13. As succinctly explained by FDA Commissioner Dr. Scott Gottlieb, the FDA had:

> recently become aware of a growing number of manufacturers marketing "vaginal rejuvenation" devices to women and claiming these procedures will treat conditions and symptoms related to menopause, urinary incontinence or sexual function. The procedures use lasers and other energy-based devices to destroy or reshape vaginal tissue. These products have serious risks and don't have adequate evidence to support their use for these purposes. We are deeply concerned women are being harmed.

Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to safeguard women's health from deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation", dated July 30, 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615130.htm; *see also* FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication, dated July 30, 2018, available at https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm (text of warning) ("July 30, 2018 FDA Warning") (emphasis added).

14. As Commissioner Gottlieb further explained, while the FDA had cleared various laser and other energy-based devices to treat such conditions as abnormal or pre-cancerous cervical or vaginal tissue or genital warts, "the safety and effectiveness of these devices hasn't been evaluated or confirmed by the FDA for 'vaginal rejuvenation.'" *Id.* Nonetheless, companies who produce and sell these devices make "deceptive health claims" and engage in "deceptive marketing of a dangerous procedure with no proven benefit," which he stated was, in a word, "egregious." *Id.* As the July 30, 2018 FDA Warning itself stated, using such devices for vaginal rejuvenation "may lead to serious adverse events," including vaginal burns, scarring,

pain during sexual intercourse, and recurring/chronic pain. July 30, 2018 FDA Warning.

15. Cynosure was one of the companies the FDA was referring to in its July 30, 2018 FDA Warning with regard to its marketing of its energy-based laser – the MonaLisa Touch.

16. In a letter dated July 24, 2018 to Cynosure, the FDA raised a number of examples of Cynosure's improper marketing of its MonaLisa Touch to treat the vaginal symptoms of menopause which the FDA could hardly have been clearer – are purposes for which it was not approved by the FDA and for which its safety and effectiveness had not been established. The FDA stated that the MonaLisa Touch had only been cleared "for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery." July 24, 2018 Letter from Cesar A. Perez, PhD, Chief of the Surveillance and Enforcement Brach, Division of Premarket and Labeling Compliance, Office of Compliance, Center for Devices and Radiological Health to Connie Hoy, Official Correspondent, Cynosure, Inc.

17. On or about July 30, 2018, Plaintiff became aware of the July 30, 2018 FDA Warning, which revealed to him for the first time that the MonaLisa Touch was not FDA approved for the purposes for which Defendants sold the MonaLisa Touch to Plaintiff and the treatments for which Defendant's Sales Representative represented to Plaintiff (the treatment of the symptoms of VVA). Upon learning the July 30, 2018 FDA Warning, Plaintiff justifiably ceased using the device due to the FDA warnings and lack of FDA approval. At the time, Plaintiff had patients who had not completed their MonaLisa Touch treatments (three are typical) but Plaintiff would not complete their treatments because they had determined to no longer use

the machine. Plaintiff therefore refunded these patients some money they had paid.

18. Had Plaintiff been aware that the MonaLisa Touch was not FDA approved for the treatments for which Defendants marketed the device to them (the treatment of the symptoms of VVA), he would not have purchased the MonaLisa Touch or agreed to finance that purchase. Plaintiff purchased the MonaLisa Touch strictly for the procedures that were marketed by Defendant as being approved by the FDA (the treatment of the symptoms of VVA), as set forth above, and for no other purpose.

19. As a result, Plaintiff has been damaged by the cost of purchasing and financing the purchase of the MonaLisa Touch at issue here and the cost of the service contract.

FIRST CAUSE OF ACTION
FRAUD

20. Plaintiff repeats, reiterates, and realleges each and every allegation contained in Paragraphs "1" through "19" inclusive of this Complaint with the same force and effect as though more fully set forth at length herein.

21. As set forth in paragraph 5 above, Defendant's agent made material misrepresentations of then existing facts to induce Plaintiff to purchase the MonaLisa Touch and finance that purchase. These representations were made with the intent and purpose to cause Plaintiff to rely upon them and purchase and finance a MonaLisa Touch.

22. Contrary to these representations, Defendant knew that the MonaLisa was not approved by the FDA to treat the symptoms of VVA at the time these representations were made or acted in reckless disregard of this fact based on, among other things, its communications with the FDA concerning approvals of the MonaLisa Touch and its procedures. Indeed, unbeknownst to Plaintiff, on or about March 17, 2015, Cynosure sought FDA approval to market its MonaLisa Touch laser for "the treatment of symptoms related to GSM including Vaginal Dryness, Vaginal

Burning, Vaginal Itching, Pain, Dysuria and Dyspareunia" but the FDA informed Cynosure on or about June 5, 2015 that these intended uses of the MonaLisa Touch raise "different safety and effectiveness questions" than the uses for which the MonaLisa Touch had previously been approved by the FDA. None of that history was made available to Plaintiff; it was not available publicly.

23. Plaintiff justifiably relied upon Defendant's representations given Defendant's superior knowledge as to what the FDA did (or did not approve) and the uses for which the MonaLisa Touch was approved by the FDA, and because it would have been unlawful for Cynosure's representatives to market the MonaLisa Touch as a treatment for the symptoms of VVA unless such marketing was approved by the FDA, in agreeing to purchase and finance the purchase of the MonaLisa Touch.

24. As a result of the Defendant's false or misleading statements, Plaintiff and Batzofin Fertility have suffered damages including the costs they have incurred (and been obligated to incur) in purchasing and financing the MonaLisa Touch. Plaintiff Batzofin would not have purchased or financed the MonaLisa Touch at a cost of almost $200,000 had he not been misled by Defendant that the MonaLisa Touch was FDA approved to treat the symptoms of VVA.

SECOND CAUSE OF ACTION
UNJUST ENRICHMENT

25. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "19" inclusive of this Complaint with the same force and effect as though more fully set forth at length herein.

26. Defendant has received the purchase price it charged Plaintiff to purchase the MonaLisa Touch from Ascentium Capital – the financing company Defendant arranged for

Plaintiff to use to finance the purchase. Defendant has also received $5,000 directly from Plaintiff for the one-year extension of the service contract. Plaintiff would not have incurred any of these costs had Defendant been truthful about the absence of FDA approval to treat the symptoms of VVA.

27. By virtue of its obtaining these monies paid by Plaintiff and Batzofin Fertility to purchase and service the MonaLisa Touch, Defendant has been unjustly enriched to the detriment of Plaintiff.

28. Defendant's retention of the monies it has gained through its wrongful acts and practices would be unjust considering the circumstances of their obtaining those monies.

29. It would be against equity and good conscience for Defendant to retain these funds given the misrepresentations Defendant utilized to induce Plaintiff to purchase and finance the MonaLisa Touch.

30. Defendant should be required to make restitution to Plaintiff, in an amount to be determined, of the monies Defendant has obtained from Plaintiff and Batzofin Fertility directly or indirectly by which Defendant has been unjustly enriched.

THIRD CAUSE OF ACTION
MONEYS HAD AND RECEIVED

31. Plaintiff repeats, reiterates and re-alleges each and every allegation contained in paragraphs "1" through "19" inclusive of this Complaint with the same force and effect as though more fully set forth at length herein.

32. Defendant has obtained the purchase price it charged Plaintiff to purchase the MonaLisa Touch from Ascentium Capital – the financing company Defendant arranged for Plaintiff to use to finance the purchase. Defendant has also received $5,000 directly from Plaintiff for the one-year extension of the service contract. Plaintiff would not have incurred any

of the costs had Defendant been truthful about the absence of FDA approval to treat the symptoms of VVA.

33. By virtue of its obtaining these monies paid by Plaintiff to purchase and service the MonaLisa Touch by means which are unlawful in the State of New York, Defendants have been benefited to the detriment of Plaintiff.

34. It would be against equity and good conscience for Defendant to retain these funds given the misrepresentations Defendant utilized to induce Plaintiff to purchase and finance the MonaLisa Touch.

35. Defendant should be required to make restitution to Plaintiff, in an amount to be determined, of the monies Defendant has received from Plaintiff directly or indirectly. It is against the principles of good conscience for Defendant to retain these monies without compensating Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as against the Defendant as follows:

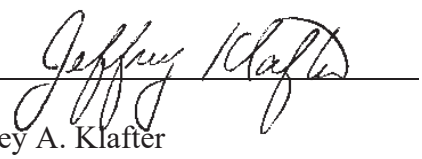
A. For compensatory, equitable and/or restitutionary damages available under the causes of actions set forth herein according to proof; and

B. For such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all questions of fact raised by the Complaint.

Dated: January 25, 2021

By: 

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